

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA,

v.

(1) STRYKER BIOTECH, LLC,  
(2) MARK PHILIP,  
(3) WILLIAM HEPPNER,  
(4) DAVID ARD and  
(5) JEFFREY WHITAKER,

Defendants.

09

CR 10.330

Criminal No.  
GAO

Violations:

- ) 18 U.S.C. §2 (aiding and abetting)  
 ) 18 U.S.C. §371 (conspiracy)  
 ) 18 U.S.C. §1001 (false statements)  
 ) 18 U.S.C. §1343 (wire fraud)  
 ) 21 U.S.C. §§331(k), 333(a)(2)  
 ) and 352 (misbranding)

INDICTMENT

The Grand Jury charges that:

General Allegations

At all times material to this Indictment, unless otherwise alleged:

The Defendants

1. **STRYKER BIOTECH, LLC** (hereinafter "**STRYKER BIOTECH**") was a limited liability corporation with a principal place of business in Hopkinton, Massachusetts. **STRYKER BIOTECH** was a subsidiary of Stryker Corporation, a company whose shares were publicly traded on the New York Stock Exchange.

2. At all relevant times, **STRYKER BIOTECH** was engaged in the manufacture and sale of medical devices for human use, including medical devices for use in healing of fractured or broken bones, including: (a) OP-1 Implant, which was an implant to promote growth in certain long bone non-unions; (b) OP-1 Putty, which was a putty to promote bone growth in

certain spinal fusions; and (c) Calstrux, which was a bone void filler for surgically created bone defects or bone defects resulting from traumatic injury. **STRYKER BIOTECH** shipped these devices in interstate commerce from its manufacturing facility in New Hampshire to many states, including Massachusetts, California, Florida, Texas, North Carolina, New York, Ohio, Michigan and others.

3. From approximately April 2004 through approximately February 28, 2008,

**MARK PHILIP ("PHILIP")** was the President of **STRYKER BIOTECH**.

4. From approximately June 2005 through the present, **WILLIAM HEPPNER** ("HEPPNER") managed the sales force of **STRYKER BIOTECH** under various titles, including National Sales Director. At relevant times, **HEPPNER** reported to **PHILIP**, and was the direct supervisor of **STRYKER BIOTECH**'s four Regional Sales Managers, who managed four sales regions – West, Central, Northeast and Southeast.

5. From approximately June 2005 through the present, **DAVID ARD** ("ARD") was the Regional Manager for the West Region of **STRYKER BIOTECH**.

6. From approximately June 2005 through the present, **JEFFREY WHITAKER** ("WHITAKER") was the Regional Manager for the Southeast Region of **STRYKER BIOTECH**.

#### The FDA and FDCA

7. The United States Food and Drug Administration ("FDA") was the federal agency of the United States responsible for protecting the health and safety of the public by enforcing the Federal Food, Drug and Cosmetic Act, ("FDCA"), 21 United States Code, Section 301, *et seq.*, and ensuring, among other things, that medical devices intended for use in humans were safe and

effective for each of their intended uses and that the labeling of such medical devices bore true and accurate information.

8. The FDCA provided that a “device” for use in humans included “an . . . implant . . . or other similar or related article . . . which is . . . intended for use in . . . the treatment or prevention of disease of man . . . or intended to affect the structure or any function of the body of man . . . which does not achieve its primary intended purposes through chemical action within or on the body of man and which is not dependent upon being metabolized for the achievement of its primary intended purposes.” 21 U.S.C. §321(h).

9. The FDCA required every manufacturer of a new device to obtain approval from the FDA prior to marketing and selling its device in interstate commerce.

10. To obtain such approval, the FDCA assigned all devices into one of three classes of devices, depending on the degree of regulatory control necessary to provide reasonable assurance of the safety and effectiveness of the device for its intended use. Class I devices were subject to the least stringent regulatory requirements, Class III devices to the most stringent, and Class II devices to requirements that fell in between Class I and Class III.

11. Devices that were not in commercial distribution prior to May 28, 1976, were classified as Class III devices, unless they were shown to be substantially equivalent to a device marketed prior to May 28, 1976. 21 U.S.C. §360c(f)(1). OP-1 Implant, OP-1 Putty, and Calstrux were not in commercial distribution prior to May 28, 1976, and were Class III devices.

12. The FDCA provided four different ways for a manufacturer to obtain approval to introduce the device intended for human use into interstate commerce:

A. Premarket Approval. Before a company could market a Class III device, that company was required to submit a premarket approval (“PMA”) application to the FDA that provided the FDA with a reasonable assurance that the device was safe and effective for its intended use. 21 U.S.C. §§360e(a)(2) and 360e(d)(2). In order to show safety and effectiveness, the applicant was required to submit evidence to the FDA, typically in the form of clinical trial results.

B. 510(k) Approval. Alternatively, a company could seek a premarket notification, commonly referred to as a “510(k)”, to the FDA seeking a determination that the device was “substantially equivalent” to a legally marketed Class I or Class II device. 21 U.S.C. §§360c(f) and (i) and 360(k). If the FDA “cleared” the device by determining that the device was substantially equivalent to a device that had demonstrated safety and efficacy, the company could market the device, which was then considered to be in the same class as the device to which it was compared. 21 U.S.C. §360c(f)(1).

C. Investigational Device Exemption. This exemption allows for clinical investigation of devices to determine safety and effectiveness for new uses. 21 U.S.C. 360j(g) and 21 C.F.R. Part 812. Submission, and subsequent approval, of an Investigational Device Exemption (“IDE”) permits a device that would otherwise be required to obtain premarket approval to be shipped lawfully in interstate commerce for the purpose of conducting clinical investigations.

D. Humanitarian Device Exemption. The fourth option to obtain approval was the submission of an application for a Humanitarian Device Exemption (“HDE”), which is similar in form and content to a PMA application, but was exempt from the effectiveness

requirements of a PMA. An HDE application was not required to contain the results of scientifically valid clinical investigations demonstrating that the device was effective for its intended purpose. The application, however, had to contain sufficient information for the FDA to determine that the device did not pose an unreasonable or significant risk of illness or injury, and that the probable benefit to health outweighed the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment. Additionally, the applicant had to demonstrate that no comparable devices were available to treat or diagnose the disease or condition, and that they could not otherwise bring the device to market. An HDE approval was accompanied by certain additional requirements:

- (1) An HDE could only be granted upon a finding by the FDA that the device was designed to treat or diagnose a disease or condition that affected fewer than 4,000 individuals in the United States.
- (2) A device approved under an HDE could not be sold for an amount that exceeded the costs of research and development, fabrication, and distribution of the device; thus, the holder of an HDE was not allowed to make a profit on the sale of an HDE device.
- (3) An HDE device could only be used at a medical facility after an institutional review board (“IRB”) at or on behalf of the medical facility approved the use of the device for the FDA approved indication; the IRBs acted as a safeguard that the HDE devices were being used properly.

13. The FDCA required that a submission for approval of a device include proposed labeling for the proposed intended uses of the device that included, among other things, the conditions for therapeutic use. A device manufacturer was not permitted to promote and market

a new device until it had an approval, including approval for the proposed labeling. Moreover, if approved, the device manufacturer was permitted to promote the device only for the medical conditions of use specified in the approved labeling. Uses not approved by the FDA were known as “unapproved” or “off-label” uses.

14. The FDCA provided that, unless otherwise exempted, a device was misbranded if, among other things, the labeling did not contain adequate directions for use. 21 U.S.C. §352(f)(1). Adequate directions for use could not be written for medical indications or uses for which the device had not been approved, and accordingly, directions for off-label use could not be included in the approved labeling. Devices that were promoted for uses that had not been approved by the FDA were deemed to be misbranded under Section 352(f)(1).

15. The FDCA prohibited the introduction into interstate commerce of any device that was misbranded, 21 U.S.C. §331(a), and also prohibited the alteration of any part of the labeling of a device while the device was held for sale after shipment in interstate commerce that resulted in the device being misbranded. 21 U.S.C. §331(k).

#### **The STRYKER BIOTECH Products**

16. Two of **STRYKER BIOTECH** products were OP-1 Implant and OP-1 Putty (collectively referred to as “OP-1 products” or “OP-1”). These two devices were part of a class of devices known as bone morphogenic proteins. These proteins had the ability to stimulate, repair and regenerate bone. OP-1 Implant and OP-1 Putty stimulated natural bone healing by actively recruiting blood supply and stem cells from surrounding tissue and thereby initiating bone formation. OP-1 Implant was designed for use in long bones, and OP-1 Putty was designed for use in the spine. The difference between the two devices was that OP-1 Implant was intended

to be used by itself in the long bones, while OP-1 Putty was comprised of both OP-1 Implant and a separate vial of 230 mg of carboxymethylcellulose, which were intended to be mixed together to form a putty to place in the spinal gutter during a spinal fusion surgery.

17. On October 17, 2001, the FDA, in response to a prior application by **STRYKER BIOTECH**, granted a Humanitarian Device Exemption or HDE for OP-1 Implant. The HDE was only for “use as an alternative to autograft in recalcitrant long bone non-unions where use of autograft is unfeasible and alternative treatments have failed.” A long bone nonunion typically referred to an arm or leg break that did not heal after conventional treatments. “Autograft” referred to bone typically harvested from a patient’s hip bone to place and stimulate bone growth in the affected site. Autograft use was unfeasible in certain patients, including elderly patients whose hip and other bones had been weakened from osteoporosis or other conditions. Thus, the medical use (also referred to as “indication”) for OP-1 Implant was narrow – it was for patients with a long bone fracture that did not heal from other treatment and for whom the use of autograft was not feasible.

18. On April 7, 2004, the FDA, in response to a prior application by **STRYKER BIOTECH**, granted an HDE for OP-1 Putty. The HDE was only for “use as an alternative to autograft in compromised patients requiring revision posterolateral (intertransverse) lumbar spinal fusion, for whom autologous bone and bone marrow harvest are not feasible or are not expected to promote fusion.” “Posterolateral lumbar spinal fusion” referred to a specific type of spinal surgery in which vertebrae in the lumbar (lower back) area of the spine were fused together. The HDE, however, was only for “revision” surgery, meaning that the patient had already had a surgery that had not succeeded in fusing the vertebrae. Moreover, the HDE was for

“use as an alternative to autograft in compromised patients. . . for whom autologous bone and bone marrow harvest are not feasible or are not expected to promote fusion.” These compromising factors included osteoporosis, smoking and diabetes. Thus, the “indication” for OP-1 Putty was narrow – it was for patients who needed a spinal lumbar fusion that had not succeeded from previous surgery and for whom the use of autograft was not feasible for a subsequent surgery.

19. **STRYKER BIOTECH** represented to the FDA that OP-1 Implant and OP-1 Putty were each designed to treat a condition that affected fewer than 4,000 individuals in the United States.

20. To obtain OP-1, hospitals either purchased it outright, or stocked it on a consignment basis. If stocked on a consignment basis, **STRYKER BIOTECH** billed the hospital for OP-1 after receiving a delivered goods receipt that indicated how many units of OP-1 were used in a particular patient during a particular surgery. The hospital paid approximately \$5000 for each unit of OP-1 Implant, and \$5250 for each unit of OP-1 Putty (the additional \$250 representing the cost of the vial of 230 mg of carboxymethylcellulose).

21. From in or about 2002 through in or about mid-2004, **STRYKER BIOTECH** received feedback from surgeons that OP-1 handled poorly (like wet sand) and did not provide enough product volume.

22. In response to these complaints, **STRYKER BIOTECH** developed Calstrux (originally named "TCP Putty"), a product with a malleable, “silly-putty” type consistency that **STRYKER BIOTECH** intended to be mixed with the OP-1 products as a “carrier” or “extender” to increase the volume and improve the handling qualities of OP-1.

23. Despite intending Calstrux to be used in a mixture with OP-1, **STRYKER BIOTECH** submitted to the FDA a Section 510(k) premarket notification of intent to market Calstrux as a bone void filler product. Bone void fillers then on the market were approved to fill voids in bones that resulted from bony defects or injury, and were not approved to be mixed with a bone morphogenic protein like OP-1.

24. On August 26, 2004, the FDA, in response to a Section 510(k) premarket notification of intent to market a bone void filler product, notified **STRYKER BIOTECH** that it could market Calstrux (originally named TCP Putty). Calstrux was approved as "a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. It is indicated for surgically created osseous [bony] defects or osseous defects resulting from traumatic injury."

25. **STRYKER BIOTECH** never applied to the FDA for approval of a mixture of OP-1 with Calstrux, nor did the FDA ever approve any such use.

26. **STRYKER BIOTECH** never performed any clinical trial in humans to determine whether a mixture of OP-1 with Calstrux was safe or effective.

27. **STRYKER BIOTECH** never formulated adequate directions for use for the mixture of OP-1 with Calstrux because the mixture was never approved by the FDA, and accordingly there was no approved labeling for such a mixture.

28. At times relevant to this Indictment, **PHILIP, HEPPNER, ARD** and **WHITAKER** each knew and understood that the FDA had not approved the mixture of OP-1 and Calstrux, that no clinical trial in humans had been conducted to determine whether the mixture of OP-1 and Calstrux was safe or effective, and that no adequate directions for use could be written for the mixture of OP-1 and Calstrux because the mixture was not FDA approved.

**Promotion of the Mixture of OP-1 and Calstrux**

29. In connection with the company-wide launch of Calstrux in early 2005, **STRYKER BIOTECH** presented Calstrux to the sales force as a “carrier” or “extender” for the OP-1 products, and **PHILIP** noted that the availability of Calstrux should “accelerate” the sales of OP-1.

30. From Calstrux’s introduction to the market, **STRYKER BIOTECH** promoted it to surgeons and surgical staff as a product to be used in combination with the OP-1 products, specifically as a “carrier” or “extender.”

31. After the launch of Calstrux, the vast majority of sales of Calstrux by **STRYKER BIOTECH** was for mixing with one of the OP-1 products.

32. **PHILIP, HEPPNER, ARD, AND WHITAKER** promoted or caused to be promoted to surgeons and surgical staff “recipes” or mixing instructions on how to combine Calstrux and OP-1. **STRYKER BIOTECH** employees advised surgeons and/or surgical staff to uses various recipes for preparing the mixture of Calstrux and OP-1. Some recommended forming the combination into “cigars,” some into “tootsie rolls,” some into “logs,” some into “bricks,” and some into “vienna sausages.” The recipes also varied in terms of amount of liquid, type of liquid (blood versus saline), and ratio of Calstrux to OP-1. As one **STRYKER BIOTECH** sales representative wrote to senior management: “Like any product if we have 30+ people doing something different with regards to mixing, dosing etc. we are going to see different results.”

33. Beginning in mid-2005, **STRYKER BIOTECH** began to receive reports of adverse events arising from a combination of the OP-1 products and Calstrux. The events

included inflammation, drainage and impaired wound healing. Some patients who experienced these adverse events had to be operated on again, and during some of these subsequent operations, surgeons observed that the OP-1/Calstrux mixture had migrated from the surgical site and looked like “oatmeal,” “grits” or “white sesame seeds.” In some instances, patients suffered from unwanted bone growth in areas to which the combination of OP-1 and Calstrux had migrated. In some instances, this unwanted bone growth had to be removed surgically.

34. In early 2006, **STRYKER BIOTECH** asked a surgeon to prepare an analysis of patients at his hospital who had been treated with a mixture of OP-1 and Calstrux. This report, which was communicated to **STRYKER BIOTECH** in or about February 2006, showed that patients who received such a mixture had an adverse event rate higher than the norm. Later that year, this same surgeon communicated to **STRYKER BIOTECH** that a mixture of OP-1 and Calstrux was not effective.

35. Despite knowing the mixture of OP-1 and Calstrux was not approved by the FDA, and despite reports of adverse events, **STRYKER BIOTECH** touted Calstrux as the “perfect carrier for OP-1” at a sales meeting in January 2006.

36. On or about February 15, 2006, a senior manager at **STRYKER BIOTECH** sent a memorandum about the mixture of OP-1 and Calstrux to other senior managers at **STRYKER BIOTECH**, including **PHILIP**, recounting concerns including, among others: (a) the adverse events from mixing OP-1 and Calstrux, (b) that a “variety of different ‘recipes’ are used” by different surgeons; and (c) that Calstrux was being improperly promoted as the “preferred carrier” for OP-I by the sales force. This senior manager further made a series of recommendations, including among others: (a) “[c]ease recommending, suggesting and preparing

for use Calstrux and OP-1 Implant as noted above. . .”, and (b) a “dear doctor” letter advising surgeons about the adverse experiences associated with the mixture of OP-1 and Calstrux.

37. After learning about the recommendation to send a “dear doctor” letter to physicians and IRBs about the adverse experiences associated with the mixture of OP-1 and Calstrux, **HEPPNER, WHITAKER**, and others in sales management argued against that disclosure in part because disclosure would: (a) harm sales of OP-1; (b) anger surgeons who had been misled because “many surgeons are just handed the product prior to implantation and think its all OP-1”; and (c) cause IRBs, whose mission was to protect patients, to cease all OP-1 usage at medical facilities at which they had previously approved the use of OP-1.

38. On or about March 1, 2006, a Vice-President of **STRYKER BIOTECH** provided training to the sales force and sales management, including **HEPPNER, ARD** and **WHITAKER**, in which he explained that the promotion of a mixture of OP-1 and Calstrux could expose the company and individual employees to criminal prosecution, and warned that:

“Consequences of ‘off-label’  
promotion

- \* Company
  - Product recall
  - FDA shut down
  - Criminal misbranding prosecution
  - Enormous criminal fines and civil penalties
- \* Individual
  - Serious offence [sic], illegal
  - Criminal prosecution and probable fines”

39. On or about March 3, 2006, **PHILIP** decided and instructed others at **STRYKER BIOTECH** that no “dear doctor” letter would be sent to surgeons advising them about adverse experiences with the mixture of OP-1 and Calstrux.

40. Despite knowing that the off-label promotion of the mixture of OP-1 and Calstrux was illegal, **PHILIP, HEPPNER, ARD** and **WHITAKER** continued to promote or cause the promotion of the mixture of OP-1 and Calstrux to surgeons and surgical staff until in or about February 2008.

**COUNTS ONE THROUGH FIVE: 18 U.S.C. §1343 – WIRE FRAUD**

41. The allegations contained in Paragraphs 1 through 40 are realleged and incorporated herein by reference.

**The Scheme to Defraud**

42. Beginning on a date unknown, but no later than in or about February 2006, and continuing until in or about February 2008, in the District of Massachusetts and elsewhere,

- (1) **STRYKER BIOTECH, LLC,**
- (2) **MARK PHILIP,**
- (3) **WILLIAM HEPPNER,**
- (4) **DAVID ARD,** and
- (5) **JEFFREY WHITAKER,**

defendants herein, devised and intended to devise a scheme and artifice to defraud physicians and hospitals and to obtain money by means of false and fraudulent pretenses, representations, and promises concerning material facts, and by concealing material facts.

**The Purpose of the Scheme**

43. The purpose of the scheme and artifice to defraud was for **STRYKER BIOTECH** to obtain millions of dollars in sales from OP-1 and Calstrux, and to enrich **PHILIP, HEPPNER, ARD** and **WHITAKER** through additional compensation from **STRYKER BIOTECH**, all through the deliberate manipulation of health care professionals with false,

deceptive, incomplete and misleading information into using OP-1 for unapproved uses, including the unapproved use of a mixture of OP-1 and Calstrux.

**Manner and Means**

44. It was part of the scheme and artifice to defraud that **STRYKER BIOTECH** developed and launched Calstrux as a product to be mixed with the OP-1 products, as a "carrier" or "extender" for the OP-1 products, despite knowing that **STRYKER BIOTECH** had never sought FDA approval for such use, that the FDA had not approved the mixture of OP-1 and Calstrux, and that no clinical trials to evaluate the safety or efficacy of the mixture of OP-1 and Calstrux had ever been performed.

45. It was further part of the scheme and artifice to defraud that **STRYKER BIOTECH** trained its sales representatives at its home office in Hopkinton, Massachusetts, that Calstrux was an "extender" for the OP-1 products, and provided them with instructions as to how to mix the two products.

46. It was a further part of the scheme and artifice to defraud that **HEPPNER**, **WHITAKER** and **ARD** trained in the field the **STRYKER BIOTECH** sales force, including representatives of affiliated companies and distributors, that Calstrux was an "extender" for the OP-1 products.

47. It was further part of the scheme and artifice to defraud that **HEPPNER**, **WHITAKER** and **ARD** trained the **STRYKER BIOTECH** sales force, including representatives of affiliated companies and distributors, regarding instructions or various "recipes" for mixing OP-1 and Calstrux.

48. It was a further part of the scheme and artifice to defraud that the **STRYKER BIOTECH** sales force, including representatives of affiliated companies and distributors, misled surgeons and surgical staff regarding the mixture of OP-1 and Calstrux in a variety of different ways in different circumstances, including by one or more of the following: (a) failing to disclose that there were adverse events arising from a combined use of Calstrux and OP-1; (b) failing to disclose that the mixture of OP-1 and Calstrux was not FDA approved; (c) failing to disclose that the mixture of OP-1 and Calstrux had never been clinically studied in humans; (d) affirmatively misrepresenting the nature of the FDA “approval” by referring to the HDE as a “steppingstone” to full approval, or telling surgeons that there was no difference between an HDE and a PMA in terms of the ability to use the product “off-label”; and (e) affirmatively misrepresenting the mixture of Calstrux and OP-1 was simply OP-1 when presented to the surgeon, and/or failing to disclose that the mixture of OP-1 and Calstrux was not simply OP-1 knowing that the surgeon so assumed.

49. It was a further part of the scheme and artifice to defraud that, from March 2006 until at least mid-2007, **PHILIP, HEPPNER, WHITAKER** and **ARD** misled the **STRYKER BIOTECH** sales force by suggesting that the adverse events associated with a mixture of OP-1 and Calstrux could be solved by merely using a “drier” mix or by using smaller sizes of Calstrux (5cc or 10cc as opposed to 15cc).

50. It was a further part of the scheme and artifice to defraud that **PHILIP, HEPPNER, WHITAKER** and **ARD** each encouraged the sales force to sell a mixture of OP-1 and Calstrux through one or more of the following mechanisms: bonuses, commissions, sales quotas, employee reviews, field training and feedback.

51. It was a further part of the scheme and artifice to defraud that **STRYKER BIOTECH** sales representatives, and sometimes sales managers, attended surgeries and directed the mixing of the Calstrux and OP-1 at surgery. When **STRYKER BIOTECH** employees could not attend surgeries, they sometimes provided or caused to be provided written mixing instructions to surgeons or surgical staff.

52. It was a further part of the scheme and artifice to defraud that **PHILIP, HEPPNER, WHITAKER and ARD** promoted or caused to be promoted a mixture of OP-1 and Calstrux through pricing proposals to hospitals and medical facilities, including those that offered combined discounted prices for purchasing OP-1 with Calstrux as an "extender."

53. It was a further part of the scheme and artifice to defraud that in early 2006 **PHILIP** obtained or caused to be obtained from a prominent surgeon in Michigan a video of this surgeon's technique for mixing OP-1 and Calstrux as a "brick," and thereafter caused the video and/or the techniques described therein to be conveyed to the **STRYKER BIOTECH** sales force.

54. It was also part of the scheme and artifice to defraud that **STRYKER BIOTECH** hired outside surgeon/consultants to promote unapproved uses of OP-1, including the mixture of OP-1 and Calstrux, through lectures at restaurants attended at various times by **WHITAKER** and **HEPPNER**.

55. It was also part of the scheme or artifice to defraud that **STRYKER BIOTECH**, hired outside surgeon/consultants to promote unapproved uses of OP-1, including the mixture of OP-1 and Calstrux, through making sales calls with the **STRYKER BIOTECH** sales force on physicians at their offices, attended one or more times by **ARD**.

56. It was a further part of the scheme and artifice to defraud that **STRYKER BIOTECH** planned and caused various meetings of physicians to take place, a purpose of which was to promote various unapproved uses of OP-1, including a mixture of OP-1 and Calstrux.

57. It was a further part of the scheme and artifice to defraud that in or about October 2006, in an effort to conceal **STRYKER BIOTECH's** role in promoting the mixture of OP-1 and Calstrux to surgeons, **HEPPNER** instructed the sales force to return to hospitals and surgical offices to retrieve copies of written mixing instructions that had been left behind.

**The Wirings**

58. On or about the dates listed below, within the District of Massachusetts and elsewhere,

- (1) **STRYKER BIOTECH, LLC,**
- (2) **MARK PHILIP,**
- (3) **WILLIAM HEPPNER,**
- (4) **DAVID ARD, and**
- (5) **JEFFREY WHITAKER,**

defendants herein, having devised and intended to devise a scheme and artifice to defraud and to obtain money and property by means of false and fraudulent pretenses, representations, and promises concerning material facts and matters, and by means of concealing material facts and matters, and for the purpose of executing such scheme and artifice and attempting to do so, knowingly transmitted and caused to be transmitted by means of wire communication in interstate commerce writings, signs, signals, pictures and sounds – to wit, on or about the dates set forth below, to recipients, including recipients in at least the states listed below, each instance being a separate count of this Indictment:

Count	Wiring	To	From	Via
1	2/14/06 e-mail from <b>WHITAKER</b> to others at <b>STRYKER BIOTECH</b> stating, among other things, "many surgeons are just handed the product prior to implantation and think its [sic] all OP-1."	IL, MO and MA	NC	MA
2	10/23/06 e-mail from <b>ARD</b> to <b>STRYKER BIOTECH</b> sales representative enclosing OP-1/Calstrux mixing instructions	MN	CA	MA
3	5/1/06 e-mail from <b>HEPPNER</b> to members of <b>STRYKER BIOTECH</b> sales force who were lagging on Calstrux sales	AZ, NY and OH	IL	MA
4	2/27/06 e-mail from <b>HEPPNER</b> to <b>PHILIP, ARD, WHITAKER</b> and others urging that a letter warning of adverse effects from a mixture of Calstrux and OP-1 not be sent	MA, CA and PA	IL	MA
5	1/15/07 e-mail from <b>PHILIP</b> to <b>HEPPNER, ARD, WHITAKER</b> and others enclosing 2007 sales budgets	NC, CA and IL	MA	MA

All in violation of 18 U.S.C. §§1343 and 2.

**COUNT SIX: 18 U.S.C. §371 – CONSPIRACY**

59. The allegations contained in Paragraphs 1 through 40 and 44 through 57 are realleged and incorporated herein by reference.

60. Beginning in or around February 2006, and continuing thereafter until at least February 2008, in the District of Massachusetts and elsewhere,

- (1) **STRYKER BIOTECH, LLC,**
- (2) **MARK PHILIP,**
- (3) **WILLIAM HEPPNER,**
- (4) **DAVID ARD, and**
- (5) **JEFFREY WHITAKER,**

knowingly and willfully did combine, conspire, confederate, and agree with each other and others, known and unknown to the grand jury, to: (a) defraud the United States, and its agency, the FDA, by impeding, impairing, obstructing and defeating through craft, trickery, deceit, and dishonest means the FDA's lawful function of regulating the manufacture and distribution of medical devices to ensure that those devices were safe and effective for their intended uses prior to commercial distribution to the American public; and (b) commit an offense against the United States, specifically, by causing written instructions to be provided for administration and use of a mixture of OP-1 and Calstrux, a use not included in the FDA-approved labeling for OP-1, while quantities of OP-1 were held for sale and after the devices had been shipped in interstate commerce, in violation of 21 U.S.C. §§331(k), 333(a)(2), and 352.

**Objective of the Conspiracy**

61. The objective of the conspiracy was to evade and frustrate efforts by the FDA to ensure the safety of medical devices by requiring adequate, well-controlled clinical studies regarding the use of such devices in humans, this objective achieved through the deliberate

manipulation of surgeons and surgical staff into using an unapproved mixture of OP-1 with Calstrux through false, deceptive, incomplete and misleading information about the device. That deliberate manipulation of surgeons and surgical personnel into using a mixture of OP-1 with Calstrux was perpetrated to obtain additional sales of a device that defendants knew was unapproved by the FDA, untested in well-controlled clinical trials, and associated with numerous adverse events. As a consequence of this manipulation, **STRYKER BIOTECH** obtained millions of dollars of sales from OP-1 and Calstrux, and **PHILIP, HEPPNER, ARD** and **WHITAKER** were enriched through additional compensation from **STRYKER BIOTECH**.

**Manner and Means of the Conspiracy**

62. It was part of the manner and means of the conspiracy that **STRYKER BIOTECH, PHILIP, HEPPNER, ARD and WHITAKER**, together with other conspirators known and unknown to the grand jury:

- a. promoted a mixture of OP-1 with Calstrux to surgeons and surgical staff;
- b. distributed to surgeons and surgical staff various written mixing instructions for mixing OP-1 with Calstrux;
- c. advised surgeons and surgical staff orally how to mix OP-1 and Calstrux;
- d. misled surgeons and surgical staff to believe that a mixture of OP-1 and Calstrux was only OP-1;
- e. encouraged the sales force through commissions, bonuses, sales quotas, employee reviews, field training and feedback to sell and promote a mixture of OP-1 and Calstrux;

- f. sponsored and held physician meetings to promote a mixture of OP-1 and Calstrux;
- g. hired surgeons as consultants to promote the mixture of OP-1 and Calstrux at both dinner meetings with other surgeons, and on sales calls to other surgeons;
- h. promoted a mixture of OP-1 and Calstrux to hospitals and medical facilities through a discounted pricing proposals for use of Calstrux as an "extender" with OP-1;
- i. prevented disclosure to IRBs, surgeons and surgical staff of information about adverse events associated with the use of the combination of OP-1 and Calstrux for the purpose of protecting sales of OP-1; and
- j. concealed the promotion of the mixture of OP-1 and Calstrux by directing the sales force to return to the hospitals to retrieve the mixing instructions that had been previously left behind for the use of the surgeons and surgical staff.

**Overt Acts**

63. In furtherance of the conspiracy, **STRYKER BIOTECH, PHILIP, HEPPNER, ARD** and **WHITAKER**, and other conspirators known and unknown to the grand jury committed among other acts in the District of Massachusetts and elsewhere:

- a. On or about March 4, 2006, following his decision not to send a "dear doctor" letter to surgeons notifying them about adverse experiences with the mixture of OP-1 and Calstrux, **PHILIP** advised a senior sales executive to "use the positive information on no Calstrux letter" to aid the sales force in achieving their March 2006 sales quotas.
- b. In or about May 2006, **STRYKER BIOTECH** hired an outside surgeon/consultant to attend sales calls on physicians with a sales representative and sales

manager in the San Francisco area, during which calls a mixture of OP-1 and Calstrux was promoted, and following which calls the outside surgeon/consultant was congratulated by **STRYKER BIOTECH** because sales were made to some surgeons, and others had specifically agreed to use OP-1 and Calstrux.

c. On or about June 28, 2006, **WHITAKER** approved a proposal to a hospital chain in Florida that included lower prices for OP-1 and a “discounted extender (Calstrux) that provides a larger volume to Infuse. . .”

d. On or about October 23, 2006, **ARD** sent a new Stryker Biotech sales representative OP-1/Calstrux mixing instructions.

e. On or about January 15, 2007, **PHILIP** sent the sales managers, including **HEPPNER, WHITAKER** and **ARD**, the sales quotas (\$68.1 million) and the “Promise to Mark [Philip]” sales figures (\$82 million) for 2007, which sales quotas which could only be reached through continued sales of a mixture of OP-1 and Calstrux.

f. In or about October 2007, **STRYKER BIOTECH** organized an “Emerging Leaders Symposium” in Chicago, Illinois, attended by **HEPPNER**, where **STRYKER BIOTECH** chose the speakers, the content of the conference, and the guest list, and at which symposium unapproved uses of OP-1, including techniques for mixing Calstrux and OP-1, were presented to the physician attendees.

g. At various times between March 2006 and December 2007, **STRYKER BIOTECH** and its conspirators provided recipes for mixing OP-1 and Calstrux to different health care professionals, and to employees of affiliated companies and distributors for delivery to health care professionals, including among instances, the following:

1. On or about March 27, 2006, a **STRYKER BIOTECH** sales representative provided a recipe for mixing OP-1 and Calstrux to Dr. H.
2. On or about October 17, 2006, a **STRYKER BIOTECH** sales representative provided a recipe for mixing OP-1 and Calstrux to Dr. P.
3. On or about October 23, 2006, **WHITAKER** provided to a **STRYKER BIOTECH** sales representative a recipe for mixing OP-1 and Calstrux for delivery to Dr. C.
4. On or about December 11, 2006, a **STRYKER BIOTECH** sales representative provided a recipe for mixing OP-1 and Calstrux to Dr. D.
5. On or about March 14, 2007, a **STRYKER BIOTECH** sales representative provided a recipe for mixing OP-1 and Calstrux to Dr. M.
6. On or about May 4, 2007, a **STRYKER BIOTECH** sales representative provided a recipe for mixing OP-1 and Calstrux to Dr. I.
7. On or about June 29, 2007, a **STRYKER BIOTECH** sales representative provided a recipe for mixing OP-1 and Calstrux to Hospital P.
8. On or about August 1, 2007, **ARD** provided to a sales representative of an affiliate a recipe for mixing OP-1 and Calstrux for delivery to Dr. R.

All in violation of 18 U.S.C. §371.

**COUNTS SEVEN THROUGH TWELVE:****21 U.S.C. §§331(k), 333(a)(2) & 352(f) -  
Distribution of a Misbranded Device**

64. The allegations contained in paragraphs 1 through 40 are realleged and incorporated herein as if set forth in full.

65. In the District of Massachusetts and elsewhere, the defendant,

(1) **STRYKER BIOTECH, LLC,**

did, while quantities of OP-1 were held for sale after the devices had been shipped in interstate commerce, and with the intent to defraud and mislead, cause written instructions to be provided for administration and use of a mixture of OP-1 and Calstrux, a use not included in the FDA-approved labeling for OP-1, which acts resulted in OP-1 being misbranded within the meaning of 21 U.S.C. §352, such instructions being provided by the sales representative to the physician and/or facility, and containing in part the content, on or about the dates set forth below:

Count	Date	Sales Rep	Doctor/ Facility	Recipe to Mix OP-1 and Calstrux
7	3/27/06	HE	Dr. H	Empty contents of Calstrux vial into OP-1 vial. Thoroughly mix two powders DRY. Add 5cc straight saline, mix, knead until all powder is incorporated.
8	10/17/06	SS	Dr. P	Combine Calstrux vial and both OP-1 vials . . . Pour all three vials into a small bowl about the size of a specimen cup and mix well to distribute the OP-1 . . . Add saline (without antibiotic solution) to the bowl and mix well . . . stir well and form into a ball of putty with your hands . . . then divide into two equal parts. Form each part into a Vienna sausage.
9	12/11/06	KL	Dr. D	Mix 2.2 cc blood with the OP-1 and 6 cc straight saline with the Calstrux (separately). Then break the Calstrux in 2 and mix one half with the OP-1, thoroughly.

<b>10</b>	3/14/07	DM	Dr. M	Empty both of the OP-1 Putty units (OP-1 and Putty Additive) into a specimen container. Add 2.5 cc of saline (or the patient's blood). Stir. Add the contents of the Bone Void Filler vial into the container. Add an additional 3cc of saline (or the patient's blood) to the specimen container. Mix the contents.
<b>11</b>	5/17/07	PG	Dr. I	Combine the entire OP-1 (BMP) bottle and the Calstrux bottle in a very small plastic or specimen cup. MIX WELL. Add approx. 4-5 cc's of blood or saline and look at mixture . . . It should look drier versus runny . . . [D]ivide the mixture in equal halves (or rolls).
<b>12</b>	6/29/07	JD	Hospital P	Dump OP-1 Putty and Calstrux into a mixing bowl. Mix contents dry first and then add 4cc's of saline (antibiotic mixed in is ok) or blood or aspirate. Continue to mix until OP-1 and Calstrux take putty form . . . then roll out into a cigar shape.

All in violation of 21 U.S.C. §§331(k), 333(a)(2), and 352(f).

**COUNT THIRTEEN:**      **21 U.S.C. §§331(k), 333(a)(2) & 352(f) - (Distribution of a Misbranded Device)**

66.     The allegations contained in Paragraphs 1 through 40 are realleged and incorporated herein as if set forth in full.
67.     On or about August 1, 2007, in the District of Massachusetts and elsewhere, the defendant,

**(4) DAVID ARD**

did, while quantities of OP-1 were held for sale after the devices had been shipped in interstate commerce, and with the intent to defraud and mislead, provide to CB, a representative for a **STRYKER BIOTECH** affiliate, for delivery to Dr. R, written instructions for administration and use of the mixture of OP-1 and Calstrux, a use not included in the FDA-approved labeling for OP-1, which acts resulted in the devices being misbranded within the meaning of 21 U.S.C. §352.

All in violation of 21 U.S.C. §§331(k), 333(a)(2), and 352(f).

**COUNT FOURTEEN:**      **21 U.S.C. §§331(k), 333(a)(2) & 352(f) - (Distribution of a Misbranded Device**

68.     The allegations contained in Paragraphs 1 through 40 are realleged and incorporated herein as if set forth in full.

69.     On or about October 23, 2006, in the District of Massachusetts and elsewhere, the defendant,

**(5) JEFFREY WHITAKER**

did, while quantities of OP-1 were held for sale after the devices had been shipped in interstate commerce, and with the intent to defraud and mislead, provide to **STRYKER BIOTECH** sales representative SS for delivery to Dr. C, written instructions for administration and use of a mixture of OP-1 and Calstrux, a use not included in the FDA-approved labeling, which acts resulted in the devices being misbranded within the meaning of 21 U.S.C. §352.

All in violation of 21 U.S.C. §§331(k), 333(a)(2) and 352(f).

**COUNT FIFTEEN: 18 U.S.C. §1001 - FALSE STATEMENT**

70. The allegations contained in paragraphs 1 through 40 are realleged and incorporated herein as if set forth in full.

71. **STRYKER BIOTECH** was obligated to submit annual reports regarding OP-1 Putty to the FDA and include in those annual reports information on the number of devices that had been shipped or sold and, if the number shipped or sold exceeded 4,000 in any year, provide an explanation and estimate of the number of devices used per patient, and the number of patients treated.

72. In the clinical trials submitted by **STRYKER BIOTECH** to the FDA, each revisionary posterolateral spinal fusion surgery involved use of 2 units of OP-1 Putty per patient, one for each side of the patient's spine. Therefore, the FDA approved label for OP-1 Putty recommended use of 2 units per revisionary posterolateral spinal fusion surgery.

73. As a practical matter, in part owing to the cost of 2 units of OP-1 Putty (in excess of \$10,000), 2 units of OP-1 Putty per patient were rarely used in spinal surgeries. Most sales of OP-1 Putty were of 1 unit per patient per surgery.

74. In 2005, **STRYKER BIOTECH** prepared various analyses of the average number of OP-1 Putty units used per patient. These analyses concluded that **STRYKER BIOTECH** was not selling an average of 2 units per patient, but rather approximately 1.3 units of OP-1 Putty per patient.

75. **STRYKER BIOTECH** knew, as early as February 2005, that based on the actual usage of OP-1 Putty, it could only sell approximately 5,000 units of OP-1 Putty per year (4,000

patients x 1.3 units/patient = 5,200 units). **STRYKER BIOTECH** also knew that there were “[s]ignificant risks associated with exceeding patient limit.”

76. However, thereafter, **STRYKER BIOTECH** undertook to sell more than 5,000 units of OP-1 Putty each year, despite knowing that based on its internal data and analyses, it could only support selling approximately 5,000 units. Selling an additional 1,000 units of OP-1 Putty in a year, for example, would generate additional annual revenue to **STRYKER BIOTECH** of approximately \$5 million.

77. By letter dated April 30, 2007, **STRYKER BIOTECH** submitted its 2007 Annual Report for Humanitarian Device Exemption #H0200008 for OP-1 Putty. That report stated as follows:

Since the last reporting period, 6234 units of OP-1 Putty have been sold to IRB-approved institutions throughout the United States. Since 2 units of OP-1 Putty are used per patient, it is estimated that 3117 patients have been treated during this reporting period.

78. On or about April 30, 2007, in the District of Massachusetts and elsewhere,

(1) **STRYKER BIOTECH, LLC**,  
defendant herein, did knowingly and willfully make a materially false statement and representation in a matter within the jurisdiction of the executive branch of the United States -- to wit, defendant **STRYKER BIOTECH** falsely reported to the FDA in its 2007 Annual Report for OP-1 Putty the number of patients that had been treated with OP-1 Putty, namely that because 6,234 units had been sold and that “[s]ince 2 units of OP-1 Putty are used per patient, it is estimated that 3117 patients have been treated during this reporting period,” when in fact

**STRYKER BIOTECH, LLC** knew that less than 2 units were used per patient and that more than 4,000 patients had been treated during that year.

All in violation of 18 U.S.C. §1001(a)(2) and 18 U.S.C. §2.

**COUNT SIXTEEN: 18 U.S.C. §1001 – FALSE STATEMENT**

79. Paragraphs 1 through 40 and 71 and of this Indictment are herein realleged and incorporated by reference.

80. During the period in or about October 2007 through in or about February 2008, within the District of Massachusetts and elsewhere,

**(2) MARK PHILIP,**

defendant herein, did knowingly and willfully falsify, conceal and cover up by trick, scheme, and device a material fact in a matter within the jurisdiction of the executive branch of the United States, namely that **STRYKER BIOTECH** was treating more than 4,000 patients per year with OP-1 Putty.

81. On or about October 11, 2007, a **STRYKER BIOTECH** employee advised **PHILIP** that in connection with an FDA inspection at **STRYKER BIOTECH** the employee had noticed that the actual usage data for OP-1 Putty did not support the assumption in the sales budget of 2 units of OP-1 Putty usage per patient, and provided **PHILIP** with an analysis prepared that day that showed that the average usage per patient was approximately 1.3 units of OP-1 Putty per patient.

82. It was a part of the scheme to conceal and cover up that on this same day, October 11, 2007, **PHILIP** contacted an outside law firm and sought a legal opinion that would justify **STRYKER BIOTECH**'s sale of 8,000 units of OP-1 Putty, instead of the amount that the **STRYKER BIOTECH** data showed was the correct amount (4,000 patients x 1.3 average units used per patient = 5,200 units). **PHILIP** failed to provide the law firm with information showing

that **STRYKER BIOTECH** had in the past accurately estimated its usage per patient and had again done so the exact day that **PHILIP** called the law firm to seek the bogus legal opinion.

83. It was a further part of the scheme to conceal and cover up that on or about November 7, 2007, defendant **PHILIP** procured a bogus legal opinion from a law firm that purported to authorize the sale of 8,000 units per year of OP-1 Putty. That legal opinion assumed falsely, based on information provided by defendant **PHILIP**, that “it could be misleading to rely upon sales records to estimate usage per patient” and that “Stryker does not currently . . . have postmarket data collection activities that would allow updated estimates on the usage per patient of either OP-1 Implant or Putty beyond the estimates derived from the approved labeling.”

84. It was a further part of the scheme to conceal and cover up that within a week of procuring the bogus legal opinion, on or about November 13, 2007, defendant **PHILIP** communicated with the lawyer who prepared it and sought his input on how to “word” the next annual report to the FDA, including what to tell the FDA about the number of patients treated with OP-1 Putty, again without providing the lawyer with information showing that **STRYKER BIOTECH** could, and recently had, accurately estimated the usage per patient of OP-1 Putty.

85. It was a further part of the scheme to conceal and cover up that on or about February 20, 2008, defendant **PHILIP**, in advance of a conference call later that day with management of Stryker Corporation, asked a colleague to say something on the call that was not true, namely that **STRYKER BIOTECH** had no way to track the per patient usage of OP-1 Putty.

All in violation of 18 U.S.C. §1001(a)(1) and 18 U.S.C. §2.

**FORFEITURE ALLEGATION**  
**(18 U.S.C. §981(a)(1)(C), 28 U.S.C. §2461(c), 18 U.S.C. §982(a)(7))**

86. Upon conviction of one or more offenses alleged in Counts 1 through 5 of this Indictment, the defendants,

- (1) **STRYKER BIOTECH, LLC,**
- (2) **MARK PHILIP,**
- (3) **WILLIAM HEPPNER,**
- (4) **DAVID ARD, and**
- (5) **JEFFREY WHITAKER,**

jointly and severally, shall forfeit to the United States, (a) pursuant to 18 U.S.C. §981(a)(1)(C) and 28 U.S.C. §2461(c), any property, real or personal, that constitutes, or is derived from, proceeds traceable to the commission of the offenses, and (b) pursuant to 18 U.S.C. §982(a)(7), any property, real or personal, that constitutes or is derived, directly or indirectly, from gross proceeds traceable to the commission of the offenses.

87. If any of the property described in paragraph 86 hereof as being forfeitable pursuant to 18 U.S.C. §981(a)(1)(C), 28 U.S.C. §2461(c), and/or 18 U.S.C. §982(a)(7) as a result of any act or omission of the defendants:

- a. cannot be located upon the exercise of due diligence;
- b. has been transferred or sold to, or deposited with a third party;
- c. has been placed beyond the jurisdiction of the court;
- d. has been substantially diminished in value; or
- e. has been commingled with other property which cannot be divided without difficulty;

it is the intention of the United States, pursuant to 28 U.S.C. §2461(c) and 18 U.S.C. §982(b)(1), incorporating 21 U.S.C. § 853(p), to seek forfeiture of all other property of the defendants up to the value of the property described in subparagraphs a through e of this paragraph.

All pursuant to 18 U.S.C. §981; 28 U.S.C. §2461(c); and 18 U.S.C. §982.

A TRUE BILL

*Maureen Camilleau*  
FOREPERSON OF THE GRAND JURY

*Jenny M. Shultz*  
ASSISTANT U.S. ATTORNEY

DISTRICT OF MASSACHUSETTS; October 28, 2009

Returned into the District Court by the Grand Jurors and filed.

*Melissa*  
DEPUTY CLERK

10/3:24 P.M.